## REMARKS

Claims 25, 27 and 30-33 are pending. Claim 25 has been amended.

Claim 25 has been amended to further clarify the Applicants' invention. Support is found on page 3, lines 27-28 of the present application.

New claim 34 has been added. Support for this claim is found in Figure 2. No new matter has been added.

***Claim Rejections under 35 U.S.C. § 103(a)***

Claims 25, 27 and 30-33 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Golomb et al. (U.S. Patent No. 6,719,998).

Golomb et al. is directed to bisphosphate and pyrophosphate complexes which are used for the prevention or treatment of restenosis. (See Abstract). The Examiner argues that the present invention, taken as a whole, would have been *prima facie* obvious given the teachings of Golomb et al. Applicants traverse for at least the following reasons.

First, claim 25 of the present invention requires "...adding polymeric particles containing a therapeutic substance to a fluid form of a[n]...coating material wherein the coating material includes a polymeric material dissolved in a solvent, and wherein the polymeric particles containing the therapeutic substance are suspended in the polymeric material dissolved in the solvent... and solidifying the coating material... by allowing the solvent to evaporate..." Nowhere does Golomb et al. disclose or suggest, either expressly or inherently, a coating material that includes a polymeric material dissolved in a solvent nor does Golomb disclose or suggest applying a fluid form of the coating material to a medical device and solidifying the coating material by allowing the solvent to evaporate.

Second, the Examiner has provided no rationale for modifying the teachings of Golomb so that it teaches the above-mentioned claim limitations. The key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. Indeed, the Supreme Court states that "Rejections on obviousness cannot be sustained by mere conclusory statements; instead,

there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness". *KSR International Co. v. Teleflex Inc.* (KSR) (550 U.S. __, 82 USPQ2d 1385, 1396) (KSR). The Examiner, however, has failed to articulate why the teaching of Golomb et al. could have been modified to teach the above claim limitations. The Examiner simply states that the invention, "when taken as a whole", would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made. The formulations of Golomb et al., however, are quite different from those of the present invention. Liposomal preparations are used to encapsulate an active ingredient. These liposomes are then delivered via various methods, including direct injection using a liquid carrier solution. Although Golomb et al. says that a stent may be coated with the "delivery system," there are no specific methods given. In the only example disclosed, an IV injection delivery is used.

Third, the Examiner is incorrect in stating that the one-polymer system in Golomb et al. is "essentially similar" to the multi-polymer method of the present invention and that there is no advantage to the multi-polymer system of the present invention. On page 5 of the Final Office Action dated April 15, 2008, the Examiner opined that "the argument that the [present invention] teaches a two-polymeric system versus the prior art which teaches a single polymeric material on the device was not persuasive since Golomb et al. explicitly teaches essentially a similar method as is instantly claimed for providing a coating on a medical device." Claim 25 requires that the polymeric particles containing the therapeutic substance are suspended in the polymeric material dissolved in the solvent. If only a single polymer system were used, as the Examiner suggests is used by Golomb et al., the solvent would dissolve the drug-loaded polymers and there would be no suspension. Thus, the multi-polymer system of the present invention serves the purpose of allowing the coating of microparticles containing a therapeutic agent onto a stent using a solvent evaporation method, something that is not even contemplated by Golomb et al., which doesn't contemplate the use of a solvent evaporation technique, much less the use of multiple polymers as coating materials for stents. The disadvantages of not having the therapeutic agents delivered by microparticles is clearly stated in the background section of the present invention on page 2, lines 20-28. These include the limited volume of drugs that can be delivered due to the limited surface area of a stent, as

well as inadequate drug release rates. Therefore, the multi-polymer compositions and techniques of the present invention are not obvious in view of the single-polymer methods disclosed by Golomb et al.

Fourth, as to the rejection of claim 30, the Examiner stated on page 6 of the Final Rejection that "Golomb teaches that where a liquid carrier is used, the preparation may be in the form of a syrup, emulsion, liposomes, etc." and that this corresponds to the water-in-oil emulsion method in claim 30. This is not a correct analysis of the Golomb et al. teachings. Golomb et al. teach that a liquid carrier, including emulsions, may be used to administer the compositions, such as a liposome preparation. (col. 6, lines 34-36). Golomb et al. does not teach that the liquid carrier, as an emulsions, may be used to make the liposome preparation, which contains the active ingredient. Therefore, Golomb et al. does not teach or suggest claim 30 of the present invention, which requires that the polymeric particles (which include a therapeutic substance) be made using a water-in-oil emulsion method. Further, the water-in-oil technique utilized by certain embodiments of the present invention is demonstrated on page 9 in Example 3. The final solution includes a polymer solution, a therapeutic substance solution, and a curing agent/photoinitiator solution. After the water-in-oil emulsion is formed, a UV lamp is used to cure (crosslink) the spherical droplets suspended in the bath, thereby forming microparticles containing a therapeutic agent. Golomb et al. does not teach or suggest 1) the use of three solutions, one of which including a curing agent/photoinitiator, and 2) crosslinking the droplets to form microparticles containing a therapeutic agent.

Fifth, as to the rejection of claim 31, the Examiner is incorrect in his reading of Golomb et al. with respect to gels and coatings. The Examiner states on page 7 of the Final Office action dated April 15, 2008 that "Golomb recognizes and teaches that their polymeric coating can be made of gel, for example, and thus would also exhibit a hydrogel consistency." Claim 31 of the present invention requires that the polymeric particles have a hydrogel consistency. Golomb et al. teach that the active ingredient may be included within a coating of the stent, where the coating may be a gel. Further, as discussed above, the multiple polymer system of the present invention provides a mechanism for allowing the polymeric particles to have a different consistency from the rest of the coating. Using the one-polymer method disclosed in Golomb et al., it is not even

clear how to achieve having only the drug particles in a hydrogel form, as opposed to just having the drug particles mixed in a gel that is the entire coating. Thus, the entire coating in Golomb et al. is a gel, as opposed to the polymeric particles of the present invention having a hydrogel consistency.

Sixth, with regard to claim 33 and the Examiner's rejection on page 7 of the final Office Action it appears that, using the Examiner's logic, no new drugs can ever be patented for treatment of condition x, if there is one drug that teaches its use for treatment of condition x. The Examiner is reminded that claim 33 depends from independent claim 25, which Applicants argue is patentable over the cited prior art.

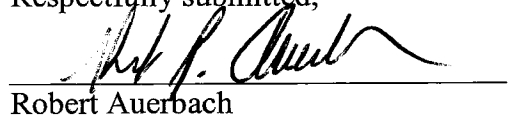
Seventh, with respect to claims 27, 30, and 31-33, because these claims depend from independent claim 25, which is not obvious in view of Golomb et al. for the reasons above, claims 27, 30, and 31-33 are not obvious over Golomb et al.

## CONCLUSION

Removal of the rejections and allowance of the claims is respectfully requested. Should the Examiner have any questions regarding this communication or any proposals with respect to the claims, the Examiner is invited to contact Robert Auerbach at (415) 954-0315.

If necessary to effect a timely response, this paper should be considered as a petition for an Extension of Time sufficient to effect a timely response, and please charge any deficiency in fees or credit any overpayments to Deposit Account No. 07-1850.

Respectfully submitted,



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